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Robert Moser, MD, Secretary

Sam Brownback, Governor

Drug Utilization Review Board
Meeting Agenda, Open Session
January 8, 2014 10:00 a.m. – 2:00 p.m.

Meeting Location
HP Enterprise Services, Capital Room
6700 SW Topeka Blvd, Bldg. 283 J, Topeka, KS 66619

Board Members

Michael Burke, MD, PhD	Russell Scheffer, MD
Tim Heston, DO	Daniel Sutherland, RPh
John Kollhoff, PharmD	Kevin Waite, PharmD
Judy McDaniel Dowd, PA-C	Roger Unruh, DO

KDHE-DHCF Staff
Brandy Allen
Kelley Melton, PharmD

HP Enterprise Services/HID Staff
Nicole Ellermeier, PharmD
Karen Kluczykowski, RPh
Nancy Perry, RN

MCO Staff
Thomas Kaye, RPh, **Sunflower State Health Plan**
Jennifer Murff, RPh, **UnitedHealthcare Community Plan**
Lisa Todd, RPh, **Amerigroup**

I. CALL TO ORDER

A. Announcements

II. OLD BUSINESS

A. Review and Approval of October 9, 2013 Meeting Minutes

III. NEW BUSINESS

A. Prior Authorization Criteria Revisions

1. **Aromatase Inhibitors (Arimidex® (anastrozole), Aromasin® (exemestane), & Femara® (letrozole)**
   The aromatase inhibitors prior authorization criteria were initially approved in July 2009 to prevent off-label use for fertility. The National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium supports several off-label uses for the aromatase inhibitors, including: endometrial cancer, uterine sarcomas, ovarian cancer for some agents, and breast cancer risk reduction for one agent. Due to the level of support in NCCN, the prior authorization criteria are being revised to include these indications.
   i. Revised Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Stelara® (ustekinumab)**
   Prior authorization criteria for Stelara were initially approved in January 2010 and revised in January 2011 and April 2012. Since the last update to the criteria, a new indication has been approved for psoriatic arthritis. Revised prior authorization criteria are being proposed to include this new indication.
   i. Revised Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Cimzia® (certolizumab pegol)**
   Prior authorization criteria for Cimzia were initially approved in July 2008 and revised in November 2008 and April 2012. Since the last update to the criteria, two new indications were approved for psoriatic arthritis and ankylosing spondylitis. Revised prior authorization criteria are being proposed to include the new indications.
   i. Revised Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Actemra® (tocilizumab)**
   Prior authorization criteria for Actemra were initially approved in April 2010 and revised in April 2012 and 2013. Since the last update to the criteria, a new subcutaneous formulation has been approved for rheumatoid arthritis. Revised prior authorization criteria are being proposed to include the new formulation.
   i. Revised Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Pulmonary Arterial Hypertension Agents (Opsumit® (macitentan))**
   Prior authorization criteria for the pulmonary arterial hypertension agents were approved in April 2013. Since the approval, a new agent has been approved by the FDA, Opsumit. Revised prior authorization criteria are being proposed to include the new agent.
   i. Revised Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Long-Acting Opioids (Zohydro ER® (hydrocodone extended-release))**
   Dose optimization limits and override criteria were initially approved for the long-acting opioids in April 2010. Since the last update to the criteria, a new agent has been approved. Revised prior authorization criteria are being proposed to include the new agent, Zohydro ER.
   i. Revised Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

B. New Prior Authorization Criteria

1. **Olysio® (simeprevir)**
   Olysio is a newly approved hepatitis C virus protease inhibitor indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. Other hepatitis C virus protease inhibitors include Victrelis and Incivek; both of these agents require prior authorization. Prior authorization criteria are being proposed to ensure use based upon FDA-approved indications.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Sovaldi® (sofosbuvir)**
   Sovaldi is a newly approved hepatitis C virus nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. Prior authorization criteria are being proposed to ensure use based upon FDA-approved indications.

   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Otrexup® (methotrexate)**
   Otrexup is a new subcutaneous formulation of methotrexate indicated for patients with rheumatoid arthritis, juvenile idiopathic arthritis, and psoriasis. Due to the cost and specific indications for the new methotrexate formulation, prior authorization criteria are being proposed to ensure use based upon FDA-approved indications.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Breo Ellipta® (fluticasone furoate/vilanterol)**
   Breo Ellipta is a new inhaled corticosteroid and long-acting beta-adrenergic agonist combination indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Brisdelle® (paroxetine)**
   Brisdelle is a selective serotonin reuptake inhibitor indicated for the treatment of vasomotor symptoms of menopause. Brisdelle is a low dose formulation of paroxetine and is not indicated for the treatment of any psychiatric condition. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Mirvaso® (brimonidine)**
   Mirvaso is a topical alpha adrenergic agonist indicated for the topical treatment of persistent facial erythema of rosacea. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Trokendi XR® (topiramate)**
   Trokendi XR is a new, extended-release formulation of topiramate. Trokendi XR is indicated for the treatment of partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut Syndrome. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Juxtapid® (lomitapide)**
   Juxtapid is a microsomal triglyceride transfer protein inhibitor indicated for patients with homozygous familial hypercholesterolemia. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Kynamro® (mipomersen sodium)**
   Kynamro is an oligonucleotide inhibitor of apolipoprotein B-100 synthesis indicated for patients with homozygous familial hypercholesterolemia. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

9. **Neumega® (oprelvekin)**
   Neumega is indicated for the prevention of severe thrombocytopenia and the reduction of the need for platelet transfusions following myelosuppressive chemotherapy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

10. **Neulasta® (pegfilgrastim)**
    Neulasta is indicated to decrease the incidence of infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
    i. Prior Authorization Criteria
    ii. *Public Comment
    iii. Board Discussion

11. **Nplate® (romiplostim)**
    Nplate is indicated for the treatment of patients with chronic immune thrombocytopenia who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.
    i. Prior Authorization Criteria
    ii. *Public Comment
    iii. Board Discussion

12. **Gilotrif® (afatinib)**
    Gilotrif is a kinase inhibitor indicated for the treatment of patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor deletions or mutations. Prior authorization criteria are being proposed to ensure appropriate utilization based on specific genetic markers.
    i. Prior Authorization Criteria
    ii. *Public Comment
    iii. Board Discussion

13. **Afinitor® (everolimus)**

Afinitor is a kinase inhibitor indicated for the treatment of breast cancer, neuroendocrine tumors of pancreatic origin, renal cell carcinoma, renal angiomyolipoma and tuberous sclerosis complex, and subependymal giant cell astrocytoma. In addition to the FDA-approved indications, NCCN Drugs & Biologics Compendia supports the use of Afinitor for Waldenstrom's macroglobulinemia and lung neuroendocrine tumors. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information and NCCN supported uses.

i. Prior Authorization Criteria
ii. *Public Comment
iii. Board Discussion

B. Miscellaneous Items

II. OPEN PUBLIC COMMENT

III. ADJOURN

Lunch will be provided for the DUR Board members.
The next DUR Board meeting is scheduled for April 9, 2014.

*Public comment is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion.
Informal comments will be accepted from members of the audience at various points in the agenda.
****THIS AGENDA IS SUBJECT TO CHANGE****